510(k) Summary
510(k) Number K101181

JUL 19 2011

TAKARA BELMONT CORPORATION
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Date Prepared: April 19, 2010
Contact: Tomokuni Hasegawa, Senior VP

1. **Identification of the Device:**
   Proprietary-Trade Name: Bel-Cat Dental Cone Beam CT
   Classification Name: Computed Tomography X-Ray System Product Code 90 OAS
   Common/Usual Name: Dental CT

2. **Equivalent legally marketed device:** TAKARA BELMONT Alphard K072574

3. **Indications for Use (intended use)** Bel-Cat is an x-ray device (cone beam computed tomography) that acquires a single 360 degree rotational sequence of the head and neck areas, including the ENT and dentomaxillofacial area for use in diagnostic support. The device is operated and used by physicians, dentists, and x-ray technologists. (Not for mammographic use.)

4. **Description of the Device:** The Bel-Cat series is a set of arm type X-ray CT diagnostic devices which has exposure modes can be customized to meet a wide variety of diverse diagnostic imaging needs. The Bel-Cat series is a true all-in-one system capable of offering diverse acquisition modes that deliver the high-definition images demanded in dental fields.

Model	Bel-Cat	Bel-Cat PA	Bel-Cat CM
Exposure modes			
CCD Panoramic			
CCD Cephalometric			
FPD Panoramic			
CT			

5. **Safety and Effectiveness, comparison to predicate device.** The results of bench, test laboratory and clinical testing indicates that the new device is as safe and effective as the predicate devices.

6. **Substantial Equivalence Chart**

Model	**TAKARA BELMONT Alphard K072574**	**TAKARA BELMONT Bel-Cat**
Indication for use	An x-ray device (cone beam computed tomography) that acquires a single 360 degree rotational sequence of the head and neck areas, including the ENT and dentomaxillofacial area for use in diagnostic support. The device is operated and used by physicians, dentists, and x-ray technologists.	SAME
Specification comparison	Focal spot: 0.6mm×0.6mm Tube voltage 60-100 kV Tube current: 2-15 mA Exposure time: 17 sec maximum Input: 3 kVa Power supply: AC 220 v, 50/60 Hz. Projection mode: CT, Panoramic Detector dimension: Two sizes available: Varian 2520: 250mm x 200mm Pixel size 127µm x 127µm 1536 x 1920 pixels Varian 3030, 300mm x 300mm, Pixel size 194µm x 194µm 1536 x 1536 pixels	Focal spot: 0.5mm×0.5mm Tube voltage 60-95 kV Tube current: 2-12 mA Exposure time: 17 sec maximum Input: 2 kVa Power supply: AC 220 v, 50/60 Hz. Projection mode: CT, Panoramic Detector dimension: Two sizes available: Varian 2520: 250mm x 200mm Pixel size 127µm x 127µm 1536 x 1920 pixels Varian 1313, 130mm x130mm, Pixel size 127µm x 127µm 1024 x 1024 pixels

7. Conclusion

After analyzing both bench test data as well as external laboratory testing to applicable standards, it is the conclusion of Takara Belmont Corporation that the Bel-Cat Dental Cone Beam CT System is as safe and effective as the predicate device, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Takara Blemont Corp.
% Mr. Daniel Kamm, P.E.
Regulatory Engineer, Submission Correspondent
Kamm & Associates
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NAPLES FL 34114

JUL 19 2011

Re: K101181
Trade/Device Name: Bel-Cat (various models)
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: OAS
Dated: May 25, 2011
Received: May 27, 2011

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101181

Device Name: Bel-Cat (various models)

Indications For Use:
This is an x-ray device (cone beam computed tomography) that acquires a single 360 degree rotational sequence of the head and neck areas, including the ENT and dentomaxillofacial area for use in diagnostic support. The device is operated and used by physicians, dentists, and x-ray technologists. Not for mammographic use.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____. (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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